I. Organization Compliance with State Law and Preemption of Federal Law

1. State Licensure and Scope of Licensure (§422.400)

Section 1855 of the Act requires that a potential M+C organization be organized and licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits in every State in which it wishes to offer an M+C plan. (An exception to the licensure requirement is made for PSOs, as provided for in part 422, subpart H.) Section 1855(b) of the Act specifies that, with limited exceptions, an M+C organization must assume full financial risk for the cost of the health services it provides under its contract. Thus, the licensure requirement is a two-pronged requirement, and any potential M+C organization must meet both prongs, such that it is licensed, and is assuming the appropriate risk level for its license.

To establish the licensure status of potential M+C organizations, and in particular to determine compliance with the requirement that the organization's M+C contract falls within the scope of its licensure, we require that new M+C applicants supply documentation from the appropriate State regulatory authorities that the organization meets both the licensure and scope of licensure requirements. In the case of noncommercially licensed

entities, §422.400(b) requires that they obtain a certification from the State that they meet appropriate solvency standards.

Comment: With regard to the scope of licensure requirements, one commenter has asked for clarification as to whether managed care organizations with enrollment limited to Medicaid beneficiaries are eligible for M+C contracts. Another is concerned about States licensing organizations to offer more than one M+C plan, noting that States may not have the resources to monitor multiple plans from multiple organizations. Other commenters have asked for clarification as to what happens if a State does not license insurers to offer high-deductible MSA plans, or does not license preferred provider organizations (PPOs). These commenters wish to know how MSA and PPO plans would be available in States which do not authorize these types of options. A commenter also asked whether States may require, for licensure purposes, that M+C organizations offer only products with "gatekeepers." The commenter believes that these requirements should be preempted in order to permit managed care organizations to offer more choices to Medicare beneficiaries.

Response: Section 1855(a)(1) of the Act requires that an M+C organization be organized and licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits in any State in which it offers an M+C plan. As

discussed in detail in the interim final rule (63 FR 35011), an entity does not have to have a commercial license to offer the type of M+C plan it seeks to offer under the M+C program. Rather, the entity must demonstrate that it is authorized by the State to assume the risk involved in offering the type of plan it wishes to offer. Thus, in the case of an organization that is authorized by the State to assume risk under a Medicaid contract, but is not commercially licensed, the State in which the organization wishes to offer an M+C plan would have to certify that the organization has authority to assume the risk involved in offering the M+C plan in question (e.g., by meeting State solvency requirements). In some States, Medicaid-contracting managed care organizations are operated under the authority of the State Medicaid agency, and the State may take the position that this authority is limited to assuming risk for Medicaid beneficiaries. Since the statute requires that M+C organizations (with the exception of PSOs) be licensed by the State, the State has the discretion to make this decision.

With regard to State monitoring of M+C organizations that they license, we do not have the authority to second guess a State’s judgment concerning the sufficiency of its resources to monitor M+C plans for which it has given authorization. The States have the sole authority for licensure of M+C

organizations, and can set their own standards for monitoring conditions of licensure.

The question of availability of MSA plans in States that do not approve high-deductible plans again goes back to the question of licensure. An organization wishing to offer an MSA plan must be licensed as a risk-bearing entity eligible to offer health insurance or health benefits in the State in question. If the organization wishes to offer a high-deductible policy as part of an MSA plan, the organization must be authorized by the State to assume risk, and under §422.400(c)(1), must demonstrate that it is authorized to offer a high-deductible policy to Medicare beneficiaries under an M+C contract. This does not mean that it must be authorized by the State to offer such a policy commercially in the State.

With regard to the availability of PPOs in States that do not have a category of licensure into which PPOs would fit, the organization again would have to demonstrate that it was licensed as a risk-bearing entity or otherwise authorized to assume risk, and that it was authorized by the State to offer a PPO product to Medicare enrollees. (We note that under new section 1852(e)(2)(D), for purposes of the applicability of certain quality assurance requirements, a PPO is defined as an entity that is not licensed as an HMO.) If a State does not have a

category for a PPO product, an organization may not offer a PPO product in that State unless it is able to demonstrate that the State has authorized it to do so in the context of an M+C contract. This same analysis applies to the question of whether a State may only allow products with "gatekeepers." If the State only has licensure categories for "gatekeeper" products, then only those products may be offered in the State, absent State authorization of an alternative product in the M+C context.

The only exception to the above requirements that the State authorize the M+C organization to offer the type of plan at issue is the exception provided by Congress for PSOs that are unable to obtain a State license.

2. Federal Preemption of State Law (§422.402)

a. General Preemption (§ 422.402(a))

Section 1856(b)(3)(A) of the Act reflects the general principle that under the supremacy clause of the constitution, State laws are "preempted" when they conflict with applicable Federal laws. Specifically, section 1856(b)(3)(A) of the Act provides that "any State law or regulation" with respect to M+C plans is superseded "to the extent such law or regulation is inconsistent" with M+C standards. This general preemption authority does not extend to non-M+C enrollees or non-M+C lines of business or activities. We apply this provision in the same

manner that Executive Order 12612 on Federalism was applied to managed care organizations with contracts under section 1876 of the Act prior to the BBA. Under that Executive Order (recently superseded by Executive Order 13132; see section VI.1 below), the requirements of section 1876 of the Act did not preempt a State law or standard unless the law or standard was in direct conflict with Federal law. Put another way, if a State law required a managed care organization to do something that it would be permitted to do under section 1876 of the Act, there was no preemption. As discussed below, new Executive Order 13132 (64 FR 43255) contains this same standard for general preemption. The general preemption rule in section 1856(b)(3)(A) of the Act is implemented in §422.402(a).

Comment: A commenter asked whether State laws that are more restrictive than Federal laws are preempted under our general preemption authority at §422.402(a).

Response: In its description of the House bill's provision for preemption of State laws "inconsistent with" the new BBA standards, the BBA Conference Report (H. Rept. 105-217, page 637) makes clear that this provision (which was retained in the conference agreement) "should not be construed as superseding a state law or regulation. . . that provides consumer protections in addition to, or more stringent than, those provided under [the

BBA]." We thus believe it is clear that Congress expected the States, in some cases, to have more rigorous or more comprehensive standards for quality and consumer protection that would enhance, rather than be subsumed under, the M+C standards for quality and consumer protection. Except when one of the "specific preemptions" discussed below applies, State laws or standards that are more strict than the M+C standards would not be preempted unless they are in conflict with (for example, would preclude compliance with) M+C requirements.

Comment: One commenter representing many plans argues that our interpretation of general preemption is too narrow, and that it should be broadened to encompass State laws that the commenter believes serve as obstacles to the purposes and objectives of the M+C program. This commenter suggests that there are situations in which compliance with both a Federal law and a State law is theoretically possible, but the administrative burdens associated with dual compliance would be tremendous, making compliance counterproductive in terms of meeting the goals of the M+C program. In these situations, the commenter believes that the State requirements should be preempted, thus relieving the burden of dual compliance.

Response: As just noted above, the legislative history of section 1856(b)(3)(A) of the Act makes clear that Congress

contemplated that M+C organizations would be subject to State requirements that were "more stringent" than M+C standards. We believe that Congress intended in section 1856(b)(3)(A) of the Act to incorporate the basic principles of Federalism, as applied to section 1876 contractors at the time the BBA was passed. We do not believe that the fact that a burden may be involved in complying with State laws makes those laws "inconsistent" with Federal requirements. We therefore believe that under section 1856(b)(3)(A) of the Act, only State standards that prevent compliance with Federal standards are preempted under this general preemption provision. As noted earlier, this position is also consistent with new Executive Order 13132.

Comment: Many commenters sought clarification of the basic principles of general preemption, and asked whether specific issues are covered under the general preemption authority of section 1856 of the Act. Some of these commenters suggested that consumer protection standards should be left to the States. For example, a commenter representing many States believes that the following types of standards are not subject to general preemption: market conduct evaluation; complaint handling (except to the extent specifically preempted by the BBA as discussed below); enforcement of unfair claim settlement practice standards (except to the extent specifically preempted by BBA);

enforcement actions generally; filing and review of policy forms and rate filings; filing and review of advertising and marketing materials; provider access standards; credentialing standards; filing and review of provider contracts; utilization review programs and standards; quality assurance programs; supplemental benefits and cost-sharing arrangements; network adequacy; enforcement of loss ratio standards; standards and enforcement of commission limitations; and provider licensing and regulation. In addition, other commenters have asked for clarification as to whether or to what extent Medicare Secondary Payer mental health parity requirements are preempted. Another commenter suggested that we interpret general preemption as covering all State laws except for financial solvency standards.

Response: We agree that the areas mentioned by the commenter would not be preempted under the general preemption rule in section 1852(b)(3)(A) of the Act, as long as the State law did not conflict with an M+C requirement. In most of the areas mentioned, if an M+C organization could comply with State law without compliance resulting in a violation of an M+C requirement, there would be no preemption. While the commenter has recognized that some of the above-referenced areas of State regulation are subject to the specific preemption provision discussed below (see the second and third items in the above

list), there are other areas among those identified by the commenter that are subject to specific preemption as well. For example, State regulation of supplemental benefits would be preempted under the specific preemption of State laws relating to benefits. In addition, some "provider regulation" could be preempted under the specific preemption of laws relating to the inclusion or treatment of providers. Thus, while we agree with the commenter that laws in the specified areas would not be preempted under section 1856(b)(3)(A) of the Act absent a conflict with M+C standards, the commenter should consult the discussion below concerning specific preemption of State laws in the areas referenced in section 1856(b)(3)(B) of the Act. With respect to the comment that all areas should be subject to general preemption except solvency, we disagree with this comment. As noted above, we believe that general preemption would only apply in the case of a specific conflict with M+C requirements.

Comment: A commenter asked for clarification as to whether and how State M+C laws apply to employee groups.

Response: As noted in the preamble to the June 26, 1998 M+C interim final rule (63 FR 35013), there is neither general nor specific Federal preemption of State requirements that apply to arrangements between employers and M+C organizations for the

provision of negotiated group benefits not covered under an M+C plan. These are purely private benefits that fall outside the scope of the M+C program and the ACR process. Thus, if there are applicable State laws not preempted by the Employee Retirement Income Security Act of 1974, these State laws could apply to employer group benefits, and would not be preempted by M+C standards. M+C standards apply only to M+C plan benefits, including: (1) Medicare-covered benefits; (2) additional benefits paid for with Medicare payments; and (3) both optional and mandatory supplemental benefits for which a premium is charged.

Comment: A commenter asked whether State confidentiality laws are preempted.

Response: General preemption applies to confidentiality requirements. Thus, just as with other consumer protection standards, State requirements that are more stringent than the new M+C standards would not be preempted, unless compliance with the State confidentiality requirements made compliance with the Federal requirements impossible.

b. Specific Preemption (§422.402(b))

There are three areas in which section 1856(b)(3) of the Act provides for specific (rather than general) Federal preemption of State law: benefit requirements; requirements relating to

treatment and inclusion of providers; and coverage determinations (including related appeals and grievance processes.) In the BBA Conference Report (H. Rept. 105-217, page 638), the conferees noted that benefit requirements, provider participation requirements, and coverage determinations (and related appeals mechanisms) are governed exclusively by Medicare standards under original Medicare, and expressed their view that this should be the case under the M+C program as well. That is, under original Medicare, States cannot specify what must be included as a Medicare benefit; States do not specify the conditions of participation for Medicare providers (though they license providers and practitioners and determine their scope of practice); States may not specify how a coverage determination is made with respect to whether or not the Medicare program covers a benefit; and States do not determine the type of appeal mechanism that is used to appeal a coverage decision made by a Medicare carrier or intermediary with respect to a Medicare benefit. In the specific preemption provisions in section 1856(b)(3)(B) of the Act, Congress provided that States similarly cannot regulate M+C plans in these areas. As in the case of general preemption, these specific preemption provisions do not extend to non-M+C enrollees, activities, or lines of business of the managed care organization.

In the interim final rule (63 FR 35012), we stated our intention to adopt a narrow interpretation of the applicability of the three areas of specific preemption, thus giving States maximum flexibility within the parameters of the statutory language. (As discussed below, this view is consistent with new Executive Order 13132 on Federalism.) We identified the following examples of areas in which State standards would be preempted:

- Benefit mandates (note that we did not interpret a limit on cost-sharing to be a "benefit").
- Appeals and grievances with respect to M+C coverage determinations.
- Requirements relating to the inclusion of providers (such as "any willing provider" laws or requirements to included specific types of providers within a plan's provider network). We note that State laws providing enrollees with a right to directly access providers are considered to provide a "benefit" to enrollees, and to affect the "inclusion" and the "treatment of" providers, and thus also are specifically preempted.

Comment: In the interim final rule, we solicited comments on whether the specific preemption of benefits should be extended to cost-sharing requirements, and if there were particular types of cost-sharing that should, or should not, be included under the

benefits preemption. We received many comments on this issue. Most industry commenters recommended that we include all State cost-sharing standards within the benefit preemption. They believe that cost-sharing is an integral part of a benefit; that the cost to a beneficiary for a particular service weighs on how much of a benefit he or she is actually receiving; and that the cost-sharing formula is what gives a benefit its market value. Commenters also argued that preempting State cost-sharing requirements would reduce variation in benefit packages, thus making comparison easier for beneficiaries, and easing the administrative burden on organizations that offer plans across State lines. They asserted that not preempting State cost-sharing standards would severely impede M+C organization's efforts to offer national plans. Another commenter wrote that it was unclear whether a State could continue to apply some of its benefit-related provisions, such as limits on copayments, State coordination of benefits and subrogation rules, and required benefit differentials for PPOs.

In contrast, commenters representing the States and beneficiary advocacy groups recommended that we continue to construe the benefit preemption as narrowly as possible, and thus not change our policy to consider cost-sharing a part of a benefit for preemption purposes. They supported our existing

policy of generally not preempting State cost-sharing requirements. One commenter believed that even benefit requirements should not be preempted, however, arguing that if States cannot mandate certain benefits, then beneficiaries in M+C plans might have different, lesser benefits than beneficiaries with original Medicare and a Medigap policy.

Response: In the interim final rule, we stated that the specific preemption of benefit requirements does not extend to State cost-sharing standards (63 FR 35013). As discussed in detail in that rule, our position was that a State law establishing limits on cost-sharing generally, or limits on cost-sharing that can be imposed for a particular benefit, would not fall under the benefit preemption as we have defined the term "benefit." We recognize that this is a narrow interpretation of the term "benefit," and that we could have interpreted "benefit requirements" to extend to limits on cost-sharing. However, we wanted to minimize the extent to which beneficiary protections enacted by a State were preempted by Federal law. This decision is consistent with our support for beneficiary rights, as well as new Executive Order 13132 on Federalism, which calls for granting States the maximum flexibility permitted under Federal law. If the benefit to which State cost-sharing limits apply is not a Medicare-covered benefit, the State standard would apply only if

the M+C organization chooses to offer the benefit, since any State mandate that the benefit be offered would be specifically preempted. Thus, to the extent that limits on cost-sharing are linked to a benefit mandate, the State cost-sharing limits could be seen to be "indirectly" preempted, in that the obligation to provide the benefit to which they apply is preempted. To the extent that an M+C organization offers the benefit to which State cost-sharing limits apply (whether as part of the package of Medicare-covered services, or as an additional or supplemental benefit), State cost-sharing standards would remain in effect unless they would be preempted under the general preemption authority discussed above.

Comment: Several commenters representing the State of Massachusetts wrote to request that we reconsider our position that the BBA prohibits State-mandated benefit laws, particularly when such a benefit is neither required by, nor funded by, the Federal government. These commenters believe that where Federal money is not involved, there is no preemption of State law, and that the M+C regulations should be modified accordingly. These commenters were particularly concerned about the effect of Federal preemption on Massachusetts' mandated prescription drug benefit, and pointed out that M+C enrollees in the State will not have access to a comprehensive prescription drug benefit in the

absence of the State mandate. The commenters noted both that there is no Federal prescription drug benefit, and that the cost of the Massachusetts benefit is borne in no way by the Federal government.

Response: Throughout the development of the interim final rule and during the summer of 1998, we discussed in depth with Massachusetts officials the effect that Federal preemption would have on the prescription drug benefit in Massachusetts. Although we recognized the State's concerns, we did not believe that the statute permitted any discretion on the issue, absent a legislative amendment. We believe that the reference to "benefit requirements" must refer to non-Medicare benefits like those at issue in Massachusetts, since, as noted above, States have never been permitted to mandate what is covered by Medicare. In September of 1998, the Massachusetts Association of Health Plans sued the Commonwealth of Massachusetts, in an attempt to resolve the apparent conflict between the State and Federal regulatory approaches. A Federal court ruled that the specific preemption in section 1856(b)(3)(B) of the Act did apply to the Massachusetts drug benefit. The State appealed, and on October 8, 1999, the ruling was affirmed by the United States Court of Appeals for the First Circuit. *Massachusetts Assn. of HMOs v. Ruthardt,* 194 F.3d 176 (1st Cir., Oct. 8, 1999). The Court found

that the M+C regulations "dominate these particular fields, leaving no room therein for State standard-setting" for benefit requirements (194 F.3d, at 183). We agree with the Court's conclusions.

Comment: Several commenters have asked us to revise §422.402 to exempt State "return home" laws from preemption under sections 1856(b)(3)(B)(i) or (ii) of the Act. These laws generally allow a hospitalized beneficiary, who lived in a retirement home that includes a Medicare-approved nursing facility, to return to this "home" facility for post-hospitalization skilled nursing services, even if that facility is not part of his/her managed care plan's network. Commenters argued that these types of provisions are not benefits requirements and are not related to treatment and inclusion of providers, but rather are consumer protection requirements.

Response: As discussed above, section 1856(b)(3)(B)(ii) of the Act clearly establishes Federal preemption for requirements relating to the inclusion or treatment of providers. We believe that a law granting an enrollee the right to coverage from a particular provider would certainly have to be considered a requirement "relating to the inclusion or treatment of providers," since it requires that the provider in question be

"included" in the network of providers through which covered services may be obtained.

As a matter of policy, we believe that return home laws have value for beneficiaries, families, and communities, and we encourage M+C organizations to offer a return home option where it would not adversely affect quality or continuity of care, and does not pose an unreasonable administrative burden. However, absent legislative change, we do not believe that the statutory preemption provisions permit any alternative interpretation that would allow enforcement of these State laws for M+C enrollees. We are exploring developing a legislative proposal to establish a limited exception to the M+C preemption provisions to accommodate State return home laws.

Comment: Several commenters offered differing opinions of our interpretation that section 1856(b)(3)(B) of the Act preempts direct access laws. Again, some commenters believe that these requirements are contract or consumer protection laws, and should not be subject to specific preemption; other commenters believe that direct access laws are clearly and specifically preempted. One commenter asked for clarification on the specific preemption of State standards related to the "treatment and inclusion of providers and suppliers." Specifically, this commenter asked for clarification on the following situations: (1) whether the

preemption applies to State standards on how providers are paid; (2) whether State standards that are more stringent than the M+C provider antidiscrimination provisions in existing §422.204(b) are preempted; (3) whether State requirements that certain categories of health professionals must be treated the same as other providers by an HMO or insurer are preempted.

Another commenter asserted that "any willing provider laws," specific benefit requirements, and requirements for the inclusion of specific types of providers should not be preempted. This commenter believes that if State standards are more stringent than Federal standards and not inconsistent with them, they should not be preempted, regardless of whether these standards relate to the areas specifically preempted by Congress.

Response: In the interim final rule, we indicated that direct access laws and any willing provider laws were illustrative of the types of laws that we believe Congress intended to preempt through the BBA's specific preemption provisions. Although we recognize that these types of State standards may be viewed as consumer protections, we believe that such standards clearly also involve both plan benefits and the treatment and inclusion of providers, and therefore are specifically preempted. With regard to the specific questions raised by the commenter, these standards all appear to involve

the inclusion or treatment of providers. In order to make a final determination, however, we would have to review the specific State law in question.

Comment: A commenter asked for clarification regarding whether certain aspects of State law, such as State definitions of medical necessity, and requirements that subscribers be notified of the right to file complaints with State regulators, would be preempted under §422.402(b)(3), which preempts State requirements for coverage determinations, including appeals and related grievances.

Response: For the purposes of coverage determinations, a State definition of "medical necessity" is preempted under §422.402(b)(3) because any such definition is integral to the determination of coverage. A State's general complaint process, as distinct from a process for appealing coverage decisions, would be subject only to general preemption under §422.402(a), not specific preemption under §422.402(b)(3). The State should indicate, however, that its process is separate, and that if the complaint involves a coverage determination, the sole mechanism for resolution is the Federal appeals process outlined in subpart M of part 422. For more information on this issue, please see guidelines issued by the National Association of Insurance Commissioners (NAIC).

Comment: A commenter who was generally supportive of Federal preemption argued that the regulations fail to clarify the ramifications of such preemption at the State level. The commenter requested that we "formalize the process" with the relevant State entities, so that managed care organizations are not held liable by a State for noncompliance with a State mandate when the organization is acting in accordance with Federal regulations.

Response: The NAIC and our staff have developed guidelines for use by the States in developing and implementing their managed care regulations and operational policies. We believe that these guidelines should address the commenter's concerns about formalized guidance for States.

Comment: Many commenters support a broader interpretation of Federal preemption such that State law related to grievance procedures would be preempted. Other commenters believe that Congress intended to specifically preempt State grievance procedures.

Response: The statute says only that grievances related to coverage determinations are subject to specific preemption; therefore, we do not believe that Congress intended to preempt all State grievance procedures. We believe that Congress recognizes that many States use the term "grievance" to describe

a complaint or define a process that constitutes an "appeal" under Medicare. Thus, we believe that the intent of the statute was to specifically preempt State requirements for grievances related only to coverage determinations, and to apply general preemption to State requirements for all other types of grievances. Thus, the State requirement would stand so long as it is not inconsistent with a Federal requirement, as discussed in detail above.

Since enrollees may have complaints that involve matters unrelated to coverage determinations, there needs to be a mechanism in place to address other types of complaints involving the manner in which enrollees receive care. Therefore, M+C organizations are required to have a grievance process in place to handle complaints unrelated to coverage determinations.

The preamble to the interim final rule alerted the public that we would establish a grievance procedure through proposed rulemaking, and sought comments on ways to make it meaningful. Until publication of that proposed rule, M+C organizations should look to State requirements for resolving complaints unrelated to coverage determinations.

Comment: A commenter asked for clarification as to whether a State law requiring the external review of all coverage determinations where the independent reviewer’s decision would be

binding on the M+C organization would be preempted under the specific preemption rules.

Response: Specific preemption would apply in that situation. The M+C appeals process is the only method that can result in a binding decision on the M+C organization. A State may choose to require external review of coverage determinations for monitoring or licensure purposes, but the requirement would be preempted to the extent that it requires a decision by any entity other than one prescribed under the M+C appeals process.

Comment: A commenter asked that we revisit our position that State tort or contract remedies may be available to beneficiaries whose coverage determination dispute goes through the Medicare appeals process. This commenter believes that coverage determination cases are contract disputes, and therefore should be the sole province of the Medicare appeals process.

Response: In some cases, a case that is cast as a State contract claim may amount to a claim that services are covered under an organization's M+C contract. We agree with the commenter that in that case, the claim would be pre-empted. However, there are other tort or State contract law, or consumer protection-based claims that would be entirely independent of the issue of whether services are required under M+C provisions. For example, a State consumer protection law may provide that certain

claims made by an HMO in advertising give rise to particular obligations under State law, that exist independent of the question of what the HMO's M+C contract requires. In other cases, a tort action may exist independent of the question of whether services are covered under an M+C contract. We believe that under principles of Federalism, and Executive Order 13132 on Federalism, which requires us to construe preemption narrowly, a beneficiary should still have State remedies available in cases in which the legal issue before the court is something other than the question of whether services are covered under the terms of an M+C contract.

3. Prohibition on State Premium Taxes (§422.404)

Section 1854(g) of the Act provides that "no State may impose a premium tax or similar tax with respect to payments to M+C organizations under section 1853." This prohibition does not apply to enrollee premium payments made to M+C plans, which are authorized under section 1854 of the Act. Section 402.404(a) sets forth the statutory provision, and specifies that the term "State" includes any political subdivision or other governmental authority within a State.

Section 422.404(b) clarifies the scope of what constitutes a prohibited premium tax, establishing that the prohibition generally does not apply to a generally applicable tax on the net

income or profits of any business. As noted in the preamble to the interim final rule, if the tax applies to premium revenue specifically, there is no exception to the prohibition of such a tax, based on the purpose of the tax.

Comment: One commenter agreed with our interpretation that the term "State" should include all political subdivisions, and recommended that we retain the regulatory language prohibiting State-levied taxes on payments made by Medicare to M+C organizations.

Response: We agree with the commenter. Since counties and other political subdivisions of a State derive their powers from the State, we believe this broad interpretation of the term "State" is the intended and necessary interpretation of the statutory provision. Thus, any prohibitions of State actions contained in Federal statute should be interpreted as prohibitions on actions at any level of State government or any State or local governmental body within the State.

Comment: One commenter noted that section 1854(g) of the Act prohibits only a "premium tax or other similar tax," and argued that this does not support our inclusion of "fees and other similar assessments" in the regulatory language at §422.404(a). The commenter argued that assessments to fund State high risk pools should be permitted.

Response: We believe that any mandatory fee or assessment imposed on premium revenues clearly would fall within the reference to a premium tax or "other similar tax." As noted in the preamble to the interim final rule, we considered whether to exempt an assessment that is used for purposes of an insolvency insurance pool, but determined that if the assessment was mandatory, it amounted to a tax. We noted, however, that an M+C organization that wished to rely on the proceeds from such a pool as part of its plan for insolvency protection could voluntarily contribute to such a pool.

Comment: A commenter objected to statements in the preamble to the interim final rule (63 FR 35014) suggesting that an M+C organization may participate in a "guaranty fund" by paying premium taxes voluntarily. The commenter pointed out that the NAIC Life and Health Insurance Guaranty Association Model Act excludes managed care organizations from its definition of a "membered insurer." The commenter recommended that we clarify that State life and health insurance guaranty associations are excepted from the preamble discussion of "guaranty funds," or at least note that under many States' life and health guaranty association laws, M+C organizations would not be considered member insurers.

Response: To the extent the commenter is referring to a guaranty fund operated by a private association, the prohibition on premium taxes would not apply. Our reference in the preamble to voluntary contribution to a guaranty fund involved a State mandated insurance pool established and operated by the government. In this case, the mandate to contribute premium revenue would be preempted, but an M+C organization could voluntarily participate.

4. Medigap

Section 1882 of the Act governs the sale of Medicare supplemental ("Medigap") policies, private health insurance policies that are designed to cover certain out-of-pocket costs incurred by Medicare beneficiaries. With minor exceptions, a Medigap policy cannot be sold in any State unless it conforms to one of ten standardized benefit packages, labeled plans "A" through "J".

Before enactment of the BBA, Federal law provided for only one opportunity for a Medicare beneficiary to purchase a Medicare supplemental ("Medigap") policy on a "guaranteed issue" basis. (Generally, this term means that the Medigap insurer cannot deny the application, delay the issuance or effective date of the policy, or charge an additional amount based on the individual's health status.) This opportunity occurs only during the 6-month

period beginning with the date the beneficiary is both age 65 or older and enrolled in Medicare Part B.

Section 4031 of the BBA amended section 1882(s) of the Social Security Act to specify additional situations in which beneficiaries are able, as of July 1, 1998, to buy specific types of Medigap policies on a guaranteed issue basis, if they apply within 63 days of losing certain other types of health coverage, and if they submit evidence of the date that the prior coverage terminated. The law also requires that the entity that provided the prior coverage advise the beneficiary of these rights. While the M+C regulations do not implement the Medigap provisions of the BBA or the BBRA, it is important to understand the implications for M+C organizations, since some situations addressed by the Medigap provisions involve beneficiaries who leave M+C plans and return to original Medicare.

The situations that give rise to the obligation to notify the beneficiary include, for example, termination of coverage by an M+C plan, reduction in an M+C plan's service area, termination of the M+C plan’s contract by us, or loss of coverage under an M+C plan due to a change in the beneficiary’s place of residence. As mentioned previously, section 501(a) of the BBRA amended section 1882(s)(3) of the Act to allow an individual to choose between two options: (1) voluntarily disenrolling before

coverage under the M+C plan is terminated involuntarily, and applying for a Medigap policy no later than 63 days after being notified by the M+C organization of the impending termination or service area reduction; or (2) waiting and applying no later than 63 days following the date of the involuntary termination or service area reduction. In these instances, the beneficiary is guaranteed the right to buy Medigap plans A, B, C, or F, subject to availability of those policies from insurers selling in the State.

With regard to availability, we note that not all 10 standardized Medigap plans may be available in all States, and all plans available in a State might not be offered by every insurer. Wisconsin, Minnesota, and Massachusetts have alternative forms of standardized policies under a waiver granted them by the Omnibus Budget Reconciliation Act of 1990 (OBRA). Federal law does not generally require sale of Medigap policies to beneficiaries under age 65 (eligible for Medicare by reason of disability or ESRD). However, State law may require insurers to sell to these populations under certain circumstances. Also, some insurers voluntarily sell policies to the disabled, usually on an underwritten basis. Where an insurer has filed in a State to sell to the under 65 population, these policies are subject to the BBA guaranteed issue protections.

The beneficiary may also have the right to guaranteed issue of a broader selection of Medigap policies if he or she either: (1) directly enrolls in an M+C plan upon first becoming entitled to Medicare at age 65; or (2) enrolls for the first time in an M+C plan after previously having been covered under a Medigap policy, and, in both instances, later disenrolls from the M+C plan within 12 months of the effective date of the M+C enrollment. Beneficiaries who were previously enrolled in original Medicare and who purchased a Medigap policy, who disenroll from the M+C plan before the 12-month “trial” period has expired, are guaranteed the right to return to their old Medigap policy, if it is still available from their former insurer; (otherwise they have the choice of plans A, B, C, or F from any insurer). Alternatively, if an M+C plan was their first choice as newly entitled Medicare beneficiaries at age 65, and they disenroll during the first 12 months after enrolling, they have their choice of all 10 Medigap plans, including plans H, I, and J, which provide some outpatient prescription drug coverage. This broader array of choices for beneficiaries who elected an M+C plan when they first became entitled to Medicare at 65, in effect, compensates them for having forgone their 6-month Medigap open enrollment opportunity, which began when they reached age 65.

In all these cases of voluntary or involuntary terminations from an M+C plan, beneficiaries must apply for the Medigap policy of their choice, from among the options available to them, within 63 days. If they fail to act within this time period, they lose both their guaranteed issue right to purchase the policy of their choice at the standard premium rate, and their protection from pre-existing exclusion periods. Outside of this guaranty issue period, they may be able to find some Medigap insurers who are willing to sell to them, but they may not be able to purchase the policy they want. Additionally, the insurer can apply a pre-existing condition exclusion period of up to 6 months and/or charge them an additional amount based on their health status.

Because the Medigap provisions establish specific deadlines for beneficiaries who wish to take advantage of these new rights, prompt action by the M+C organizations to notify beneficiaries of their rights, or by us to provide accurate evidence of recently terminated coverage, is essential. We are committed to providing beneficiaries whose M+C coverage is terminated with timely and accurate evidence of the recently terminated coverage. To this end, we will provide M+C plans with, among other things, a model final termination letter that must be sent 90 days prior to termination of a contract. This letter will contain detailed

information about beneficiaries' rights to Medigap under BBA and the BBRA.

We urge M+C organizations to keep in mind that they are obligated to notify beneficiaries whose coverage terminates of their rights under the Medigap provisions. Those provisions are complex, and beneficiaries will be entitled to guaranteed issue of Medigap policies at standard premium rates and with no preexisting condition exclusion periods only under certain circumstances. As noted above, their choice of Medigap policies will depend on the precise reason for, and timing of, the termination of their coverage under the M+C plan. It also matters whether they disenroll voluntarily or wait to be involuntarily disenrolled. However, if their initial 12-month trial period will expire before the M+C plan's contract will terminate, they have the option of disenrolling before the 12-month period has expired if they wish to obtain the broader selection of Medigap policies that may be available to them.

Further guidance is available to beneficiaries from their State Health Insurance Assistance Program (SHIP) or State insurance department.

Comment: A commenter has asked whether Medigap coverage is still applicable when a beneficiary chooses to privately contract for health services.

Response: Medigap policies cover two basic types of costs. The first includes costs such as deductibles and coinsurance that apply with respect to services covered by Medicare. The second includes costs of non-covered items and services such as outpatient prescription drugs. Medigap insurers are only required to make payment for the first type of services if a bill is submitted to and processed by Medicare. When a beneficiary privately contracts with a physician or practitioner under section 1802(b) of the Act to receive services that would otherwise be covered under Medicare, the services are excluded from Medicare payment under section 1862(a)(19) of the Act, and the beneficiary agrees not to submit a bill. As the beneficiary acknowledges in the private contract, as required by section 1802(b)(2)(B)(iv) of the Act, the Medigap policy will not pay for costs related to these services.

The policy may, however, be required to make payment with respect to the types of costs that are not otherwise covered by Medicare.

Comment: Commenters asked for clarification of the effective date of the BBA guaranteed issue requirements for Medigap A, B, C, and F plans, and for clarification of the rights of disabled beneficiaries with regard to guaranteed issue.

Response: As discussed above (and in greater detail in the **Federal Register** on December 4, 1998 and February 17, 1999, 63 FR 67078 and 64 FR 7968, respectively), the BBA's guaranteed issue provision took effect for all insurers on July 1, 1998. In addition, as noted previously, any Medigap policy that is available to beneficiaries under age 65 under any other circumstances must be offered to beneficiaries under age 65 who meet the criteria for BBA guaranteed issue protections.

Comment: One commenter was concerned about the wide variation in premiums of the 10 Medigap plans, and was worried about beneficiaries being overcharged.

Response: It is true that there is wide variation in the premiums charged for the 10 standardized Medigap policies, both within States and from State to State. Regulation of Medigap insurance rates is ultimately within the discretion of the States, although federal Medigap law imposes some general requirements. In particular, Medigap policies must meet certain loss-ratio standards that are intended to ensure that policies provide refunds or credits if aggregate premiums exceed aggregate benefits by too high a margin. In addition, during the initial open enrollment period, and when the BBA guaranteed issue situations are in effect for a beneficiary, the insurer cannot increase the premium based on the beneficiary's health status.

Comment: Commenters voiced concern over the possibility of a beneficiary being penalized when a health plan terminates without timely enough notice for the beneficiary to find the appropriate Medigap insurance. Commenters also believe that we should provide plans with information as to which States have Medigap policies without pre-existing condition limitations as of January 1, 1999, and in general that plans need more information on Medigap.

Response: We have developed a clear termination policy and systems to provide for timely beneficiary notification, so that beneficiaries will be aware of their rights and protections if a plan terminates. In addition to developing internal processes, we are working with the States and M+C organizations to develop model language that will clearly and timely inform beneficiaries of their rights and protections.

In addition, we are working with the NAIC and the States to develop the Medigap Compare database, which will identify available Medigap policies and allow beneficiaries to compare costs and benefits. Beneficiaries and M+C plans will be able to access this database to gain the appropriate information a beneficiary needs when seeking Medigap insurance.